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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0157-006.B.WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IB 03/02513	International filing date *(day/month/year)* 20.05.2003	Priority date *(day/month/year)* 20.05.2002
International Patent Classification (IPC) or both national classification and IPC A61F2/06		
Applicant UNIVERSITY OF LAUSANNE et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 9 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
28.11.2003	03.06.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Borowski, A Telephone No. +49 89 2399-2758

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/02513

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-12	as originally filed

Claims, Numbers

1-26	received on 23.04.2004 with letter of 21.04.2004

Drawings, Figures

8	as originally filed
1a-1f, 2, 3, 4, 5, 6a-6d, 7	received on 17.10.2003 with letter of 16.10.2003

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

   see separate sheet

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 22-26

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/ or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-21
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-21
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-21
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 22-26 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT (a method of treating a laryngotracheal stenosis comprising endoscopically inserting a medical device into the larynx). Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

V.1 Document **D2** is regarded as being the closest prior art to the subject-matter of claim 1, and shows a laryngotracheal stent, comprising a tubular member formed from a material having a hardness of between approximately 30° Shore-A and approximately 70° Shore-A, said tubular member having a distal end and a proximal end and extending longitudinally there between, forming a lumen there through, wherein said tubular member comprises a first portion comprising the proximal end of said tubular member and a second portion comprising the distal end of said tubular member (see Fig.1 and description: column 3, lines 50-56).

The subject-matter of claim 1 differs from this known device in that said tubular member further comprises a connecting bend formed as a junction of said first portion and said second portion, said bend forming an angle between about 90 degrees and 180 degrees, between said first portion and said second portion. The subject-matter of **claim 1 is therefore new** (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as how to provide a higher comfort to the patient. The solution to this problem proposed in **claim 1 of the present application is considered as involving an inventive step** (Article 33(3) PCT), as it is not suggested by any available prior art.

Claims 2-21 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

V.2 According to the requirements of Rule 6.4(a) and (b) PCT, claim 14 should have been drafted as dependent on (referring to) claim 13.

V.3 According to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in documents D1 and D2 should have been mentioned in the description, and these documents should have been identified therein.

V.4 The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

We claim:

1. A medical device for placement within a portion of a mammalian patient, the device comprising a tubular member formed from a substantially rigid material having a hardness of between approximately 30° Shore-A and approximately 70° Shore-A, said tubular member having a distal end and a proximal end and extending longitudinally there between, forming a lumen there through, wherein said tubular member comprises a first portion comprising the proximal end of said tubular member, a second portion comprising the distal end of said tubular member,

   characterized by the fact that said tubular member furthermore comprises a connecting bend formed at a junction of said first portion and said second portion, wherein said first portion is substantially non-cylindrical and wherein said connecting bend forms an angle between said first portion and said second portion, said connecting bend being closer to the proximal end of said tubular member relative to the distal end of said tubular member, said angle being between about 90 degrees and about 180 degrees.

2. The medical device of claim 1, wherein said angle is between about 120 degrees and about 150 degrees.

3. The medical device of claim 1, wherein said angle is about 130 degrees.

4. The medical device of claim 1, wherein said angle is about 155 degrees.

5. The medical device of claim 1, wherein said substantially rigid material is silicone.

6. The medical device of claim 1, wherein said proximal end is closed.

7. The medical device of claim 6, wherein said proximal end is substantially triangular in shape.

8. The medical device of claim 1, wherein said proximal end is open.

9. The medical device of claim 1, wherein said tubular member has an outer diameter between about 3 mm and about 20mm.

10. The medical device of claim 9, wherein said outer diameter is between about 6 mm and about 15 mm.

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11. The medical device of claim 9, wherein said outer diameter is selected from the group consisting of about 6 mm, about 7 mm, about 8 mm, about 9 mm, about 10 mm, about 11 mm, about 12 mm, about 13 mm, about 14 mm, and about 15mm.

12. The medical device of claim 1, further comprising a substantially L-shaped tracheotomy connector member, said connector member being operably connected to said tubular member.

13. The medical device of claim 1, further comprising a fixation member, said fixation member being substantially flexible, said fixation member being operably connected to said tubular member.

14. The medical device of claim 1, wherein said fixation member is a inner silicone tongue.

15. The medical device of claim 1, wherein said proximal end of said tubular member has a larger outer diameter than said distal end of said tubular member.

16. The medical device of claim 1, further comprising a substance capable of being released in a controlled manner from said device, said substance selected from the group consisting of a polypeptide growth factor, a hormone, an anti-inflammatory agent, and an anti-scar formation compound.

17. The medical device of claim 1, further comprising an anti-microbial agent.

18. The medical device of claim 1, wherein said device is substantially similar to the inner laryngotracheal contours of a human.

19. The medical device of claim 1, wherein said device is formed in the shape of a human larynx.

20. The medical device of claim 18 or 19, wherein the tubular member is bent at an angle such that its proximal end, which has an outer diameter larger than the distal end, can contact the arytenoid cartilages of the patient.

21. The medical device of claim 18 or 19, wherein the tubular member is created by molding cadaver larynges and by increasing the interarytenoid distances to obtain the intralaryngeal contours of a fully abducted larynx.

22. A method of treating a laryngotracheal stenosis, comprising:

endoscopically inserting a medical device into the larynx of a mammalian patient suffering therefrom, said medical device comprising a tubular member formed

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from a substantially rigid material having a hardness of between approximately 30° Shore-A and approximately 70° Shore-A, said tubular member having a distal end and a proximal end and extending longitudinally there between, forming a lumen there through, wherein said tubular member is substantially non-cylindrical, wherein said tubular member comprises a first portion comprising the proximal end of said tubular member, a second portion comprising the distal end of said tubular member, and a connecting bend formed at a junction of said first portion and said second portion, wherein said first portion is substantially non-cylindrical and, wherein said connecting bend forms an oblique angle between said first portion and said second portion, said connecting bend being closer to the proximal end of said tubular member relative to the distal end of said tubular member, such that said connecting bend of said tubular member contacts the arytenoid cartilages of said patient, thus maintaining the appropriate interarytenoid distance,

such that the laryngotracheal stenosis is treated upon insertion.

23. The method of claim 22, wherein said laryngotracheal stenosis is a supraglottic, glottic, subglottic or upper tracheal stenosis.

24. The method of claim 22, wherein the proximal end of the tubular member is closed.

25. The method of claim 22, wherein the proximal end of the tubular member is open.

26. The method of claim 22, wherein said medical device further comprises:

a substantially flexible fixation member, wherein said fixation member has a proximal end and a distal end, said proximal end being operably connected to said tubular member, and

a substantially L-shaped tracheotomy connector member,

whereby said method further comprises:

drawing the distal end of said fixation member through a tracheostoma of said patient and fixing said distal end to a fixation means; and

operably connecting said connector member to said tubular member.

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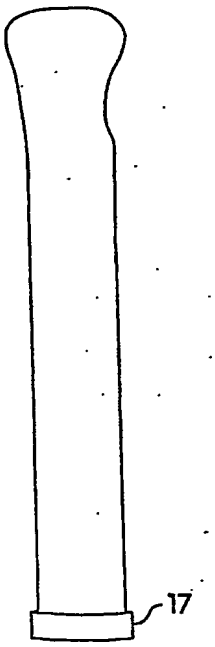

Fig. 1A

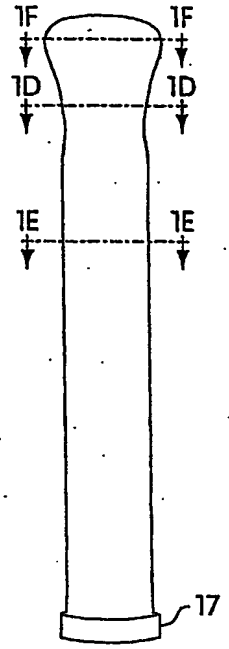

Fig. 1B

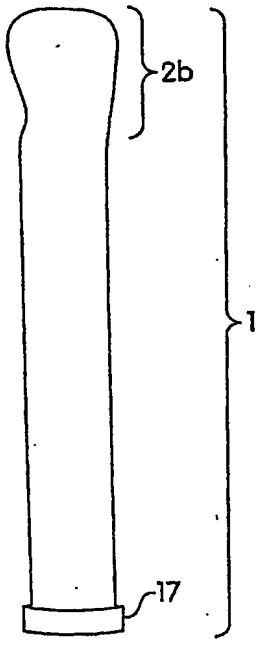

Fig. 1C

Fig. 1D

Fig. 1E

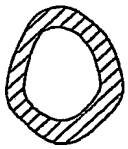

Fig. 1F

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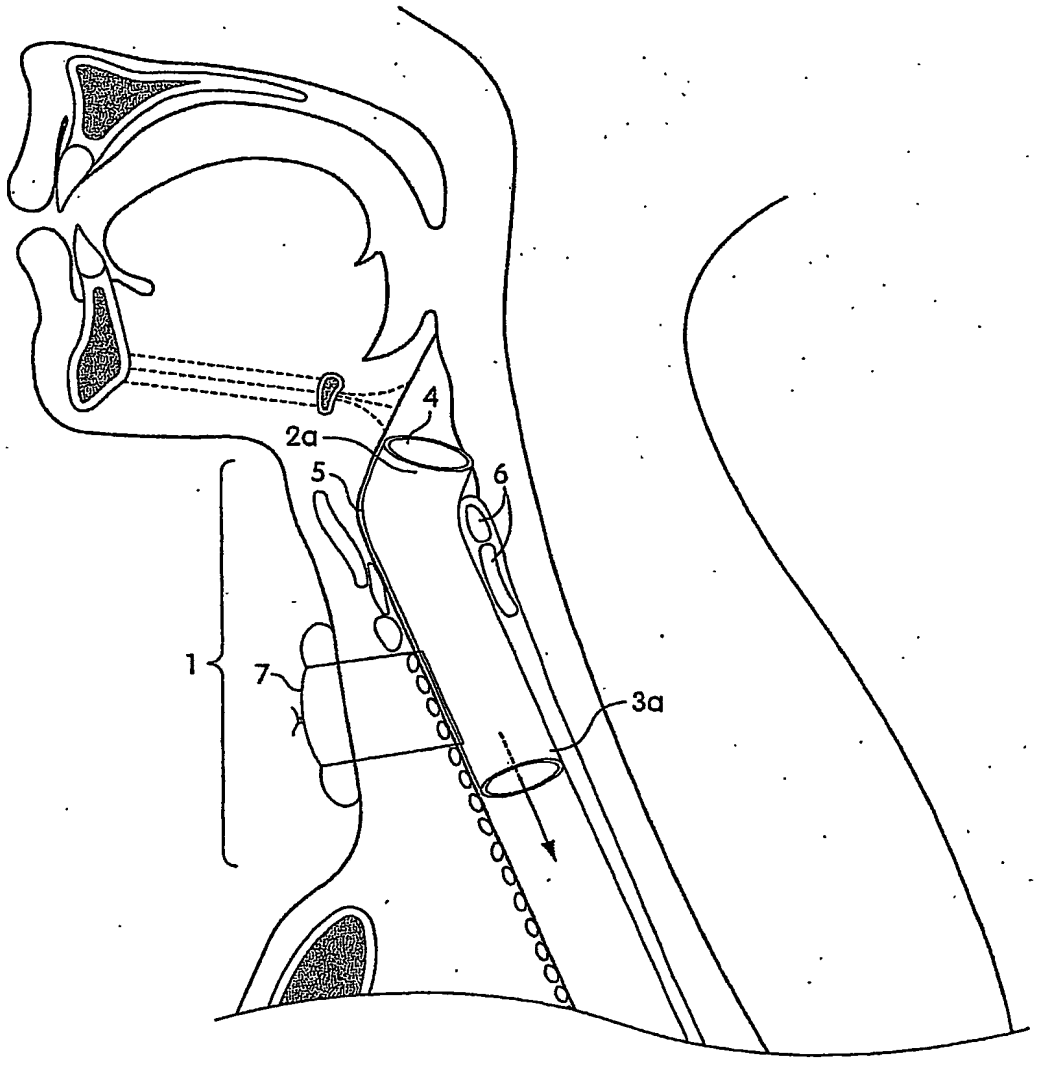

Fig. 2

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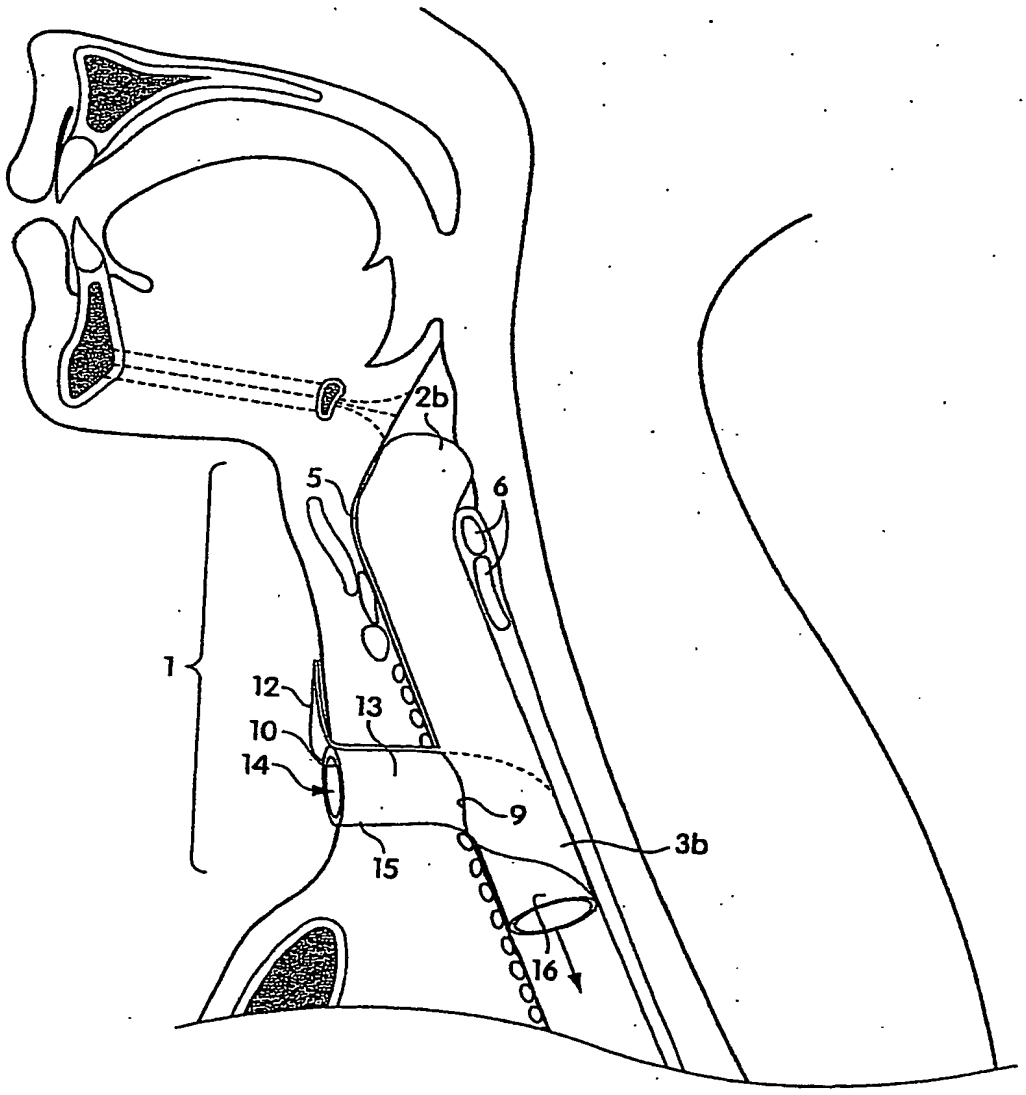

Fig. 3

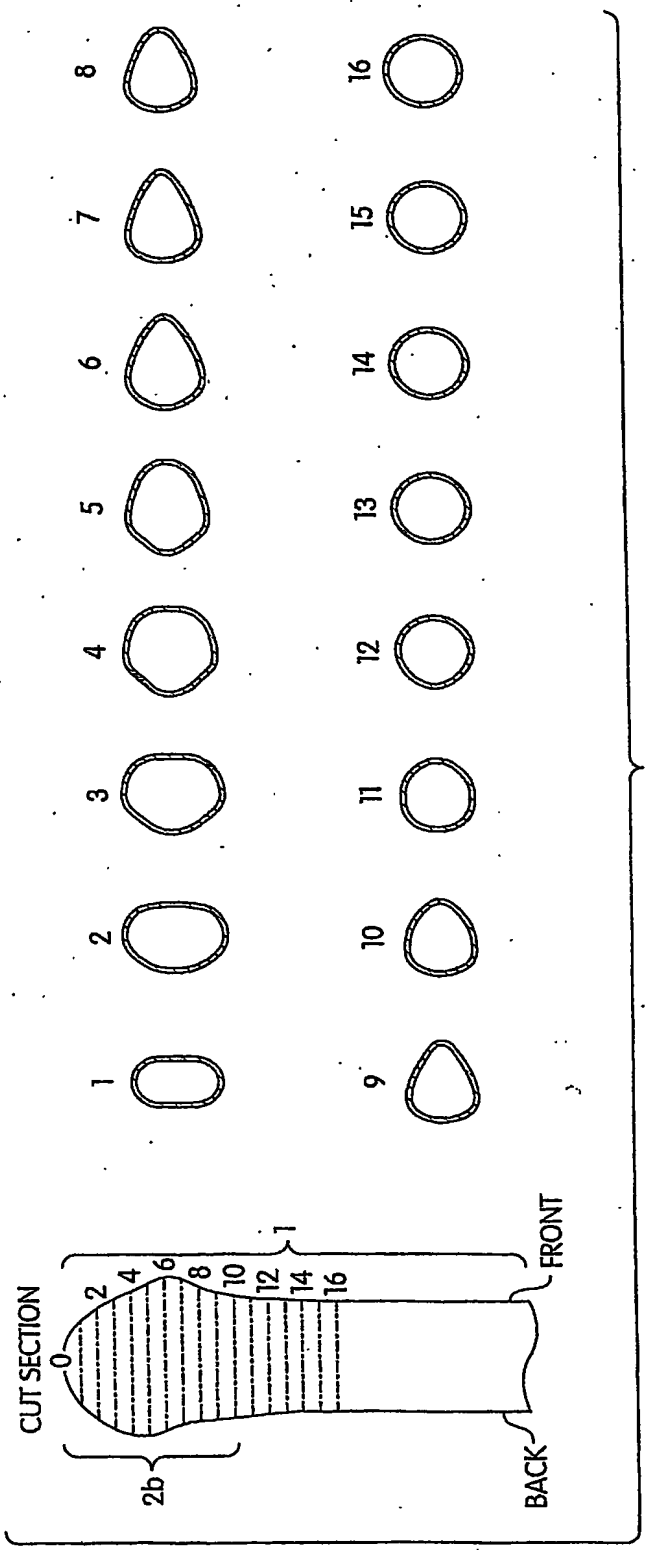
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Fig. 4

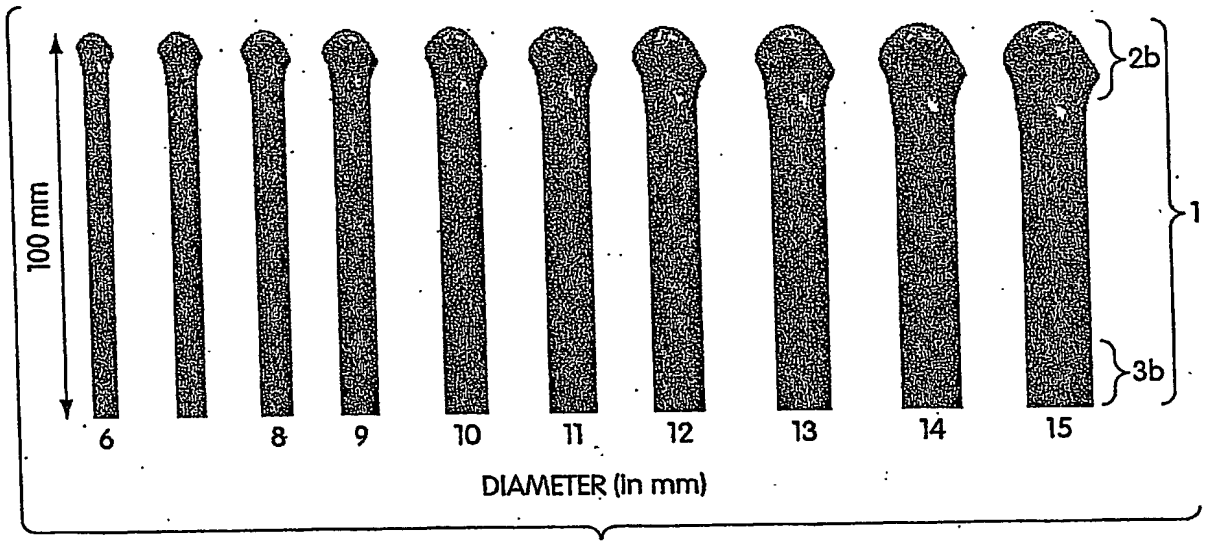

Fig. 5

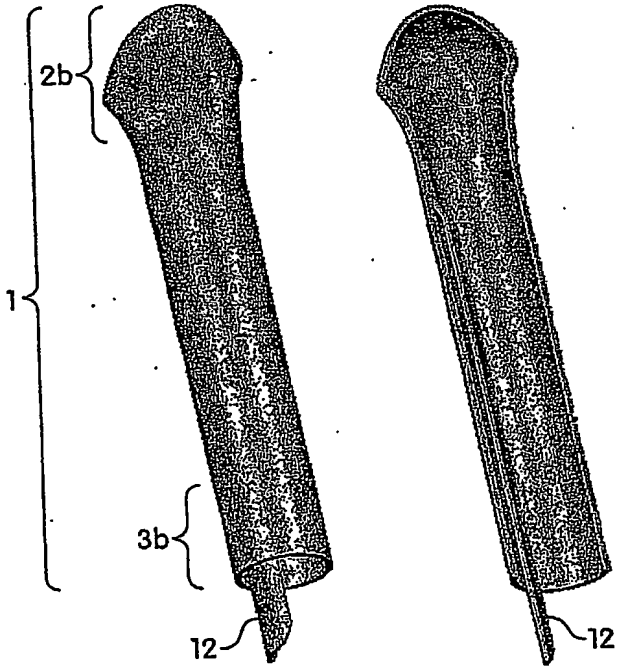

Fig. 6A

Fig. 6B

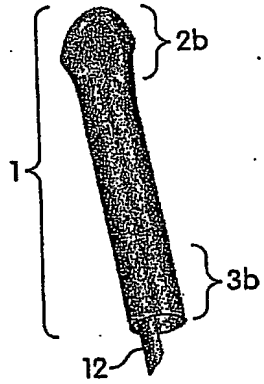

Fig. 6C

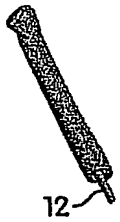

Fig. 6D

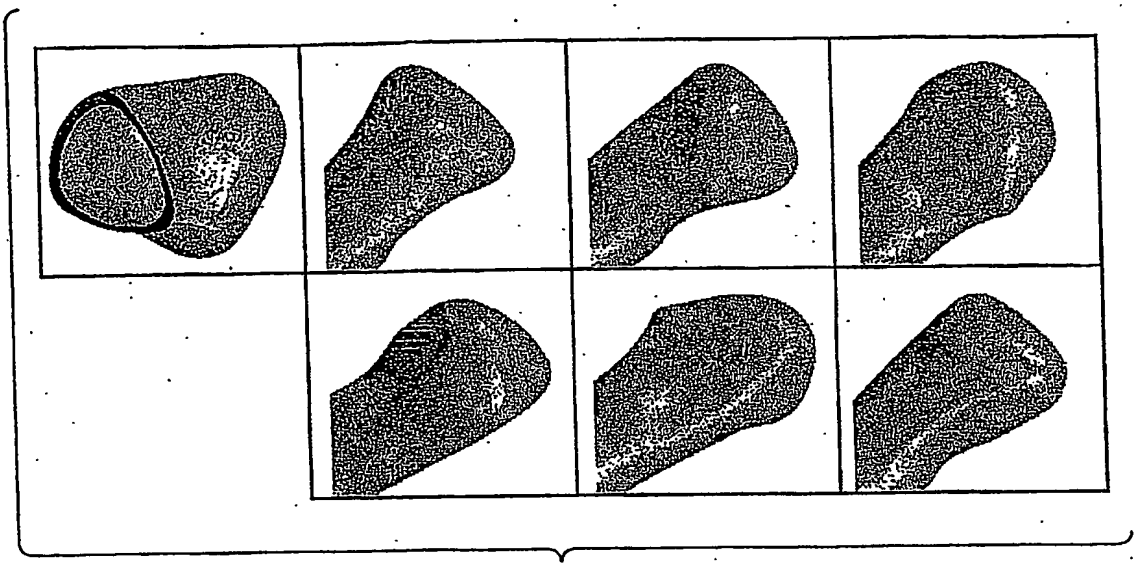

Fig. 7

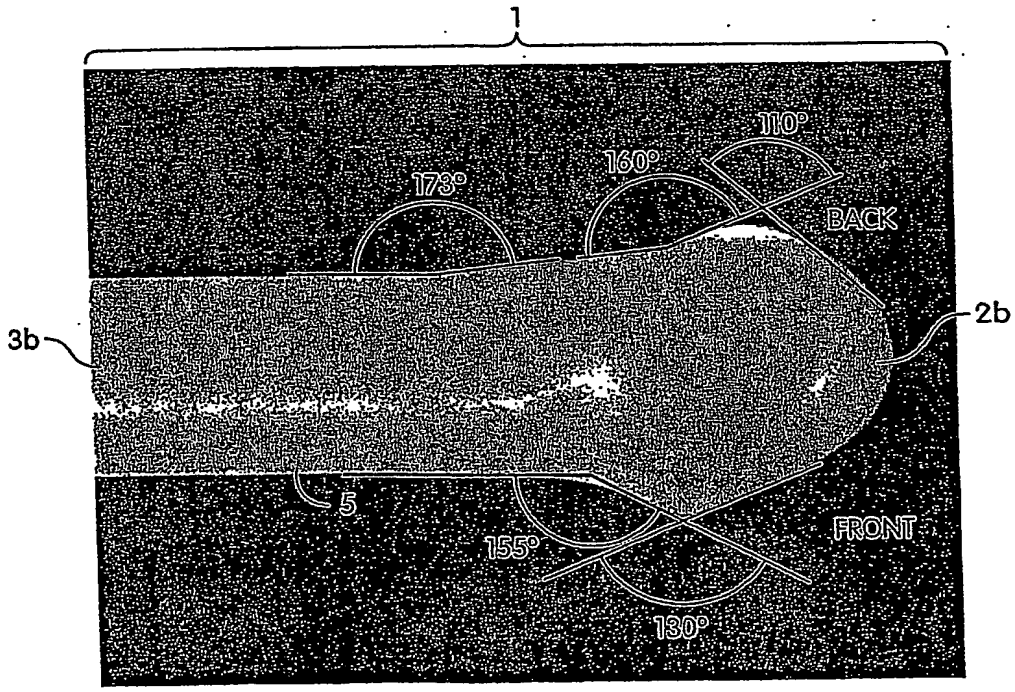

Fig. 8